OCT 2 8 2004

K042934

510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

Peter Zurlo
Manager, Regulatory Affairs

B D Medical Surgical
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Phone: 201-847-6447
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2. **Device Name:**

Trade Name: BD SoloShot IX Syringe

Common Name: Piston Syringe

Classification Name: Syringe, Piston

Predicate Device:

BD Single-Fil Syringe

Manufactured by: Becton Dickinson and Company

3. **Device Description:**

The Predicate Device, the BD Single-Fil™ Syringe **(K883955)** is a standard 3-piece piston syringe with a permanently attached needle and with an auto-disable feature that prevents reuse of the syringe after aspiration and injection by locking the plunger rod in place after injection. The syringe consists of the syringe barrel with permanently attached needle, a plunger rod and non-latex rubber stopper. The syringe is individually blister packaged and Gamma Irradiation sterilized to SAL of 10^{-6}. This syringe is intended for aspiration and injection of fluids.

The Modified Device, the subject of this 510(k), the BD SoloShot™ IX Syringe has been modified from the Predicate Device by changing to a 2-piece piston syringe. The syringe consists of a syringe barrel and one-piece plunger rod without the rubber stopper. The SoloShot™ IX Syringe has an identical permanently attached needle and identical auto-disable feature. This syringe is individually blister packaged and ETO sterilized to SAL

of 10^{-6}. The intended use of the modified device remains the same as the predicate; for aspiration and injection of fluids.

5. **Intended Use:**

Same intended use as the Predicate Device.

The BD SoloShot™ IX Syringe is intended for the Aspiration and Injection of fluids

Technological Characteristics:

The Modified Device, the subject of this 510(k), The BD SoloShot™ IX Syringe was modified by changing the plunger rod and removing the rubber plunger stopper making the syringe a 2-piece syringe (barrel and plunger rod).
The Modified Device is manufactured of the same materials, has the same intended use and SAL of 10^{-6} as the Predicate Device.

6. **Performance:**

Design Verification tests were performed based on the risk analysis performed and the results of these tests demonstrate that the BD SoloShot™ IX Syringe performed in an equivalent manner to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 8 2004

Mr. Peter Zurlo
Manager, Regulatory Affairs
Becton Dickinson Medical Surgical
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K042934
Trade/Device Name: SoloShot™ IX Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: October 22, 2004
Received: October 25, 2004

Dear Mr. Zurlo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K042934

Device Name BD SoloShot™ IX Syringe

Indications for Use The BD SoloShot™ IX Syringes are intended for the aspiration and injection of fluids.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K042934

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